

IN RE: DECLARATORY RULING)
PROCEEDING ON THE)
INTERPRETATION AND)
APPLICABILITY OF VARIOUS)
STATUTES AND REGULATIONS)
CONCERNING THE SALE OF)
CONTACT LENSES)

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The staff of the FTC was designated an intervenor in accordance with Conn. Gen. Stat. § 4-176(d) and Conn. Agencies Regs. § 19a-9-27 by the Board of Examiners for Opticians on February 13, 2002.

The questions posed by the Board raise three issues: (1) the regulation of intrastate sellers, (2) the regulation of out-of-state sellers, and (3) the adherence of all sellers to prescription requirements. The questions are phrased in a general manner, apparently covering sellers of all types of contact lenses. However, we understand that the principal controversies concern the sale of disposable replacement lenses.² In any event, our comments address the three questions in the context of replacement lenses, the lion's share of which are sold as disposable replacement lenses.

Other parties to this proceeding, such as the Connecticut Attorney General, can be expected to address more fully the proper interpretation of Connecticut law. This comment will instead focus on the core concern of the Federal Trade Commission, which is how rules adopted in this proceeding will likely affect consumer welfare.

Executive Summary

To help ascertain the possible impact of the Board's decision on consumer welfare, this submission examines the likely costs and benefits to consumers of any incremental changes in regulation and barriers to entry that may result from this proceeding. Based on the Commission's significant expertise concerning regulation and competition, and considerable experience with the eye care industry in particular, FTC staff believe that an overly restrictive interpretation of the Connecticut statutes and regulations is likely to adversely affect consumer welfare by raising prices for at least some consumers without offsetting benefits in health or safety. To summarize our analysis:

1. Existing federal and state regulations already provide significant protections for the health and safety of contact lens wearers, even if the Board imposes no new requirements in this proceeding.
2. It is likely that mandatory licensing of stand-alone sellers of replacement contact lenses would both increase prices and reduce convenience for contact lens consumers and thus adversely affect consumer welfare. The critical inquiry is whether requiring Connecticut licenses for firms who sell only replacement lenses will create sufficient new benefits for contact lens wearers to offset these adverse effects.

² Replacement contact lenses means contact lenses that are sold to replace the contact lenses prescribed by the eye care professional after the initial fitting is complete.

3. The ways in which prescription requirements are interpreted and enforced may also have competitive consequences. The staff of the FTC believe that the Board can maximize consumer welfare by following the most procompetitive approach consistent with the protection of consumers' health. In other words, it is desirable to accomplish regulatory objectives in a way that is least restrictive of innovative distribution methods.

I. Interest and experience of the FTC

In answering the questions at issue in this proceeding, the Board will no doubt wish to consider a variety of factors. One significant factor that needs to be taken into account is the impact of the Board's decisions on competition and consumer welfare. The FTC's primary expertise is in competition and consumer protection policy, and we offer these comments to assist the Board in assessing how its decisions may affect competition and consumer welfare.

The FTC's statutory mission is to protect consumers. The FTC is charged by statute with enforcing those laws that prohibit unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.³ Pursuant to this statutory mandate, the Commission encourages competition in the licensed professions to the maximum extent compatible with other state and federal goals. The Commission has extensive experience assessing the impact of regulation and business practices on competition in many regulated professions.⁴

The Commission also has significant expertise concerning competition in the eye care industry in particular and has been active in this area for nearly three decades. The Commission enforces the Ophthalmic Practice Rule ("Prescription Release Rule"), originally promulgated in 1978, which requires an optometrist or ophthalmologist to provide a patient, at no extra cost, a copy of the patient's eyeglass prescription after completion of an eye exam.⁵ In another rulemaking proceeding during the 1980s, the Commission examined other kinds of restraints on the business practices of eye care professionals and concluded that restrictions on commercial practices have caused significant injury to consumers, resulting in both monetary losses and less frequent vision care, without offsetting consumer benefits.⁶ Based on the evidence assembled in

³ Federal Trade Commission Act, 15 U.S.C. § 45.

⁴ See, e.g., *Alaska Healthcare Network, Inc.*, Docket No. C-4007 (Apr. 25, 2001); *Colegio de Cirujanos Dentistas de Puerto Rico*, Docket No. C-3953 (June 12, 2000); *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990); *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986).

⁵ 16 C.F.R. Part 456.

⁶ Ophthalmic Practice Rules ("Eyeglasses II"), Statement of Basis and Purpose, 54 Fed. Reg. 10,285, 10,286 (Mar. 13, 1989).

that rulemaking proceeding, the Commission adopted a rule that prohibits state-imposed restrictions on several types of commercial arrangements by eye care professionals.⁷ The Commission has also taken action against anticompetitive restrictions on competition in the eye care industry through administrative litigation.⁸

The Prescription Release Rule requires an optometrist or ophthalmologist to provide a patient, at no extra cost, a copy of the patient's eyeglass prescription immediately after the eye examination is completed. The Rule also prohibits optometrists and ophthalmologists from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the optometrist or ophthalmologist and from placing on the prescription, or delivering to the patient, certain disclaimers or waivers of liability. The Rule currently does not require an optometrist or ophthalmologist to release a contact lens prescription to a patient after an eye exam.⁹ However, the Rule does state that it is an unfair practice for an ophthalmologist or optometrist to condition the availability of an eye exam on a requirement that the patient agree to purchase any ophthalmic goods, including contact lenses, from the ophthalmologist or optometrist.¹⁰ In adopting the original Prescription Release Rule, the Commission found that many consumers were deterred from comparison shopping for eyeglasses because eye care practitioners refused to release prescriptions, even when asked to do so, or charged an additional fee for release of a prescription.¹¹

The Commission is conducting a review of the Prescription Release Rule, as part of its systematic review of its Rules and Guides to determine their effectiveness and impact. The Commission requested public comment about the overall costs and benefits of the Rule and related questions and received comments from numerous parties, including associations representing various segments of the industry and professions, state attorneys general, state

⁷ The Court of Appeals ultimately vacated this "Eyeglasses II" rule on the ground that the Commission lacked the statutory authority to make rules declaring these state statutes unfair. However, the Commission's findings that the restrictions harmed consumers were not disturbed. *See California State Bd. of Optometry v. FTC*, 910 F.2d 976 (D.C. Cir. 1990).

⁸ *See, e.g., Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549 (1988) (challenging Board regulation that unreasonably restricted truthful advertising by optometrists; final order required Board to allow truthful advertising and to repeal regulation).

⁹ 16 C.F.R. § 456; *see also* Ophthalmic Practice Rules, Final Trade Regulation Rule, 54 Fed. Reg. 10,285, 10,299, 10,303 (Mar. 13, 1989).

¹⁰ 16 C.F.R. §§ 456.2(b), 456.1(c).

¹¹ Advertising of Ophthalmic Goods and Services, Statement of Basis and Purpose and Final Trade Regulation Rule, 43 Fed. Reg. 23,992, 23,998 (June 2, 1978).

optometry boards, and consumers.¹² Those comments have contributed further to the Commission's expertise regarding the eye care marketplace.

II. Competition and innovation in eyewear markets have been enhanced by entry of nontraditional firms

The current proceeding stems from a decades-long evolution of the eyewear marketplace. A brief review of that evolution provides a useful context for understanding the larger policy issues involved.

The principal purpose of the Ophthalmic Practice Rules was to provide consumers a greater range of choices when buying ophthalmic goods and services. Prior to the Rule, prohibitions and restrictions on advertising of ophthalmic goods and services were commonplace; advertising of ophthalmic goods and services by either optometrists or opticians was prohibited or severely restricted by state or private regulation in every state but one.¹³ Therefore, there was virtually no price competition and a general lack of consumer knowledge concerning purchasing eyeglasses and eye exams. Comparison shopping and obtaining information about goods and services offered in the ophthalmic market was difficult or impossible.¹⁴

In contrast, competition has increased dramatically in the eye care marketplace since the 1970s. In the wake of *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,¹⁵ and other commercial speech cases, advertising of ophthalmic goods and services is now common. Chain firms have become a fixture in the optical industry marketplace, and the market share of "alternative" retail sources of contact lenses, including mail order, pharmacy and mass merchants (such as Costco and Wal-Mart), grew significantly during the 1990s. Many of these entities advertise heavily and widely, in publications, direct mail coupon packs, on television, and on the Internet.

Many significant innovations in the sale of eyewear came from the entry of nontraditional players. In some cases, the innovators offer the services of both optometrists and opticians, by employing or entering various kinds of contractual agreements with both types of professionals. In other cases, new entrants have focused on selling eyewear, relying on the customer to first

¹² See Request for Public Comments, 62 Fed. Reg. 15,865 (Apr. 3, 1997).

¹³ 1978 Statement of Basis and Purpose, *supra* note 11, 43 Fed. Reg. at 23,994.

¹⁴ *Id.* at 23,995-96; 1989 Statement of Basis and Purpose, *supra* note 6, 54 Fed. Reg. at 10,288.

¹⁵ 425 U.S. 748 (1976) (holding that the state's blanket ban on advertising prescription drug prices violated the First Amendment).

obtain a prescription from an optometrist or ophthalmologist. Both types of firms typically offer multiple types of eyewear, including eyeglasses, hard contacts, regular soft contacts, and disposable contacts.

The most recent step in the evolution of this market, and the one that brings us to the current controversy, is the development of stand-alone sellers of replacement contact lenses. Such firms tend to focus on the sale of replacement lenses. They do not sell eyeglasses. They do not fabricate lenses or fit them to the eye; they sell only replacement lenses for which the customer has already been fitted by an eye care professional. Unlike other eyewear sellers, their business consists simply of shipping to customers lenses that come from the manufacturer in sealed boxes labeled with the relevant specifications. Many of these businesses are located in a single state but ship orders to customers nationwide. Some of the largest are located outside the state of Connecticut.

Disagreements between these firms, their more traditional competitors, and contact lens manufacturers came to a head in *In re: Disposable Contact Lens Antitrust Litigation*.¹⁶ In that multidistrict litigation, the Attorneys General of 31 states and a certified class alleged that eye care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that the manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. According to the complaints, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which has hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. The parties reached settlements, the last of which the court approved in November 2001.

As part of the settlement, Johnson & Johnson agreed to sell its lenses to alternative distribution channels, as long as those firms sell lenses to customers in accordance with a valid prescription and in compliance with all federal and state laws and regulations. Johnson & Johnson petitioned the Board for this proceeding in order to clarify Connecticut's regulations, to aid Johnson & Johnson in ascertaining whether alternative lens sellers are in compliance with all Connecticut laws and regulations.

The three questions in this proceeding are phrased in a way that implies that each question has a single answer that applies to all sellers of contact lenses. However, it is clear from the historical context that the real issue is how the Connecticut laws and regulations apply to a particular type of seller: the stand-alone seller of replacement lenses that merely sells lenses and does not fabricate lenses or fit them to the eye. For this reason, we will focus on the relevant

¹⁶ *In re: Disposable Contact Lens Antitrust Litigation*, No. MDL 1030, (complaints filed M.D. Fla. 1994).

factors that should be considered in determining how the Connecticut laws and regulation should apply to firms that sell only replacement lenses. We offer no opinion on how the laws and regulations should apply to contact lens providers who also sell eyeglasses, fabricate lenses, or fit them to the eye.

III. There are significant health issues concerning the sale of contact lenses

The sale of contact lenses raises significant health issues that many current federal and state laws and regulations are intended to address. This proceeding will determine whether some of Connecticut's regulations will be applied in a more or less restrictive fashion.

To ascertain whether a more restrictive interpretation would create incremental consumer benefits, one must first consider the health issues involved in contact lens sale and use. The Board will no doubt hear evidence from a number of medical experts in this proceeding. In the interest of making the record as complete as possible, we offer a brief summary of the pertinent medical evidence concerning health issues and contact lenses that FTC staff have encountered in the course of the Commission's Rule Review and the multidistrict antitrust litigation.

The primary health care concern with contact lenses appears to be ensuring that contact lens wearers return to their doctors regularly for eye examinations. Disposable contact lenses prevent oxygen from reaching the cornea, and lack of oxygen can lead to severe eye damage. Therefore, it can be important that a patient adhere to the doctor's recommended wearing schedule, removing and replacing the lenses when recommended. Some individuals may develop eye problems even if they follow the doctor's advice; their eyes may develop problems simply in response to wearing lenses. Customers incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.

The primary means by which federal and state regulators ensure that contact lens wearers undergo periodic eye exams by qualified practitioners is to require sale of contact lenses by prescription. In contrast to prescription drugs, virtually no consumer is likely to try to "self-prescribe" vision-correcting contact lenses. Unless a consumer is willing to bear the expense of purchasing and trying on countless brands, types, and powers of contact lenses, it is impossible for the consumer to find out what to order in the absence of an optometrist's or ophthalmologist's assistance. It is thus reasonable to assume that every contact lens wearer has received a prescription for those lenses at some time.¹⁷

¹⁷ See, e.g., Supplemental Report of Gerald E. Lowther, O.D., Ph.D., on behalf of The American Optometric Association, *et al.*, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 9 ("A contact lens prescription cannot be determined until a patient has worn a diagnostic lens for some time, usually days or weeks." This is because the fit may change based on various wearing factors. "Only after this time and process can a patient be given a contact lens prescription.") See also Conn. Gen. Stat. § 20-7c(b) (practitioners must release "contact lens

For the purposes of this proceeding, it is important to note that the medical purpose of the prescription requirement (aside from describing the proper lenses) is to induce the customer to have regular eye exams – *not* to control where the customer may purchase replacement lenses with a valid prescription. The Commission's Rule review, the multidistrict litigation, and Commission staff's own consultations with industry experts have revealed no systematic evidence that sales through alternative channels, such as Internet or mail order, pose any additional health risk as long as the retailer sells in accordance with a valid prescription.¹⁸

The FDA first approved a soft contact lens in 1971.¹⁹ Beginning in the late 1980s, lens manufacturers began to market and sell "disposable" and "frequent replacement" soft lenses, which are designed to be replaced daily, weekly, or monthly. Most soft lenses are now sold in multipacks, with disposable lenses typically sold in multipacks of six lenses. When first developed, soft contact lenses were not manufactured in a way that always accurately reproduced the same prescription.²⁰ In the past 20 years, however, manufacturers have developed production methods for soft contact lenses that have eliminated these standardization problems.²¹ According to commenters during the Rule review, the soft contact lenses that a patient receives will be identical regardless of whether the patient gets the lenses from an eye care professional or from a non-traditional seller. In comments filed in the FTC's review of the Rule, the American Academy of Ophthalmology and the California Optometric Association both stated that while fabrication errors might present a problem with respect to hard contact lenses, soft lenses, such as disposables, are relatively standard and can be easily reproduced.²²

specifications based on examinations *and* final contact lens fittings" (emphasis added)).

¹⁸ There is anecdotal evidence that some customers who purchase lenses through these alternative channels developed eye problems. *See, e.g.*, Deposition of George Kenneth Johnson, O.D., filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 102-3, 168. These patients, however, purchased lenses using invalid or incorrect prescriptions. We are aware of no systematic study demonstrating that lens wearers who purchase replacement lenses through alternative channels in accordance with a valid prescription show any greater incidence of eye health problems.

¹⁹ *See* 47 Fed. Reg. 53,411, 43,415 (1982).

²⁰ *See* Report of Gerald E. Lowther, O.D., Ph.D., on behalf of The American Optometric Association, *et al.*, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 18-20.

²¹ *Id.*

²² Comment from COA, #112 at 8; Comment from AAO, #97 at 1-2. The comments from the FTC's Rule review are on file on the Commission's public record as Document Nos. B21940700001, *et seq.* The comments are cited herein by the name of the commenter, a shortened version of the comment number (the last one to three digits), and the relevant page(s)

Due to this difference, medical professionals do not always follow the same fitting and sales procedures with soft replacement lenses as they do with hard contacts. Several commenters have noted that medical practitioners do not examine the fit of each replacement lens on the patient's eye after the prescription has been finalized through the fitting process.

In fact, some lens manufacturers provide direct shipment of replacement lenses to consumers, and some eye care practitioners mail replacement contact lenses to patients without an office visit during the span of the patient's prescription.²³ Thus, the practice, *even among some traditional eyecare professionals*, suggests that replacement lenses can be marketed and delivered somewhat differently from other lenses, without adverse health effects.

Under the terms of the settlement agreement of the multidistrict litigation, the American Optometric Association explicitly agreed that it:

"shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses. Specifically, AOA shall not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order or pharmacy or drug stores."²⁴

Not surprisingly, this aspect of the settlement agreement is precisely consistent with medical evidence presented in the multidistrict litigation:

- The Wisconsin Optometric Association in 1988 repeatedly urged members to notify the association of any health problems that occurred when patients took their prescriptions and ordered lenses from a source other than the doctor. As of 1998, the association still had not received any documented reports of such health problems.²⁵
- In 1992, Vistakon (a subsidiary of Johnson & Johnson) tracked complaint calls and sorted them into various categories. Only three phone calls – 0.8 percent of the total – involved any type of link between health problems and purchases of lenses from alternative

or attachments of the comment.

²³ Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 59-64.

²⁴ Preliminary Settlement Agreement, *In re: Disposable Contact Lens Antitrust Litigation*, (filed Apr. 23, 2001, approved Nov. 1, 2001) at 1.

²⁵ Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 131-34.

channels. This is a disproportionately low percentage, since at least 5-10 percent of Vistakon lenses were sold through alternative channels in 1992.²⁶

- Multiple optometrists who testified as witnesses were asked if they knew of any scientific studies showing that consumers face greater health risks if they purchase contact lenses from a mail order firm. No optometrist could cite such a study. Several said that the source from which the consumer purchases the lens should make no difference as long as the seller follows the prescription. One ophthalmologist was quoted as saying, "If the lens comes directly from the manufacturer in a sealed container, it should not matter where that lens is obtained by the patient."²⁷
- In fact, Johnson & Johnson's own expert witness acknowledged that the "[s]teps which can be taken to minimize episodes of contact lens related complications include careful and appropriate lens selection and fitting, continuing patient education on proper lens care procedures, good hygiene, prompt reporting of symptoms by patients, and on-going monitoring and care of patients through regular aftercare visits."²⁸ Notably, none of these recommended steps involve obtaining replacement lenses directly from an optician or other eye care professional.

IV. Current federal and state regulations address contact lens health concerns

The Connecticut Board is not being asked to make its decisions in a regulatory vacuum. Existing regulatory requirements already address the primary health concerns at issue in this proceeding and ensure that appropriate safeguards will be maintained to protect consumers' health. The key question is whether there are benefits to consumers from additional, more restrictive regulations that would outweigh the substantial additional consumer costs.

A. FDA prescription requirements

Federal law on the prescription requirement for replacement contact lenses is complex and somewhat opaque. FDA regulations state that a soft contact lens is a Class II medical device if it is intended for daily wear.²⁹ Rigid gas permeable contact lenses and soft contact lenses

²⁶ *Id.*

²⁷ *Id.* at 138.

²⁸ Contact Lenses: Fitting, Follow-up and Complications, Report of A. Christopher Snyder, O.D., M.S., for The American Optometric Association, *et al.*, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 48.

²⁹ 21 C.F.R. § 886.5925(b)(1) (2001). Class II devices are devices for which "general controls" are insufficient to provide a reasonable assurance of safety and effectiveness but for

intended for extended wear are Class III medical devices.³⁰ A provision in the Food, Drug & Cosmetics Act gives the FDA the authority to promulgate a regulation to require that a device be restricted to sale, distribution, or use only upon the written or oral authorization of a licensed practitioner.³¹ Notably, there is no such regulation specifically requiring a prescription for contact lenses.³²

Nevertheless, approval documents for individual lens products state that they must be sold by prescription. Additionally, there is a general regulation that covers prescription devices overall, which states that a device which "is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared," will be exempt from the statutory labeling requirements if the device is "sold only to or on the prescription or other order of such practitioner."³³ Replacement contact lenses fall under this exemption.

The FDA also has strict labeling requirements. A device is considered misbranded if its labeling does not contain "adequate directions for use" and "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form,

which there are existing methods to provide such assurances. 21 U.S.C. § 360c(a)(B). These methods may include special guidelines, performance standards, and postmarket monitoring, but a prescription requirement is not explicitly mentioned.

³⁰ 21 C.F.R. §§ 886.5916 and 886.5925(b)(2). Class III is the most stringent regulatory category and applies to devices for which insufficient information exists to assure safety and effectiveness solely through general or special controls, but again the statute is silent as to a prescription requirement. 21 U.S.C. § 360c(a)(C)

³¹ 21 U.S.C. § 360j(e)(1) ("The Secretary may by regulation require that a device be restricted to sale, distribution, or use – (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device, or (B) upon other such conditions as the Secretary may prescribe in such regulation.").

³² The FDA regulations for Ophthalmic Devices appear at 21 C.F.R. §§ 886.1 -886.5928. None of these regulations specifies that contact lenses be restricted to sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device.

³³ 21 C.F.R. § 801.109(a)(2).

as are necessary for the protection of users”³⁴ Connecticut’s Uniform Food, Drug, and Cosmetic Act has a similar provision.³⁵

The FDA has the authority to take action against the dispensing of a prescription device without a valid prescription.³⁶ The FDA generally defers to the states on these enforcement issues. Its guide for purchasers of contact lenses over the Internet states that, “[s]ince individual states have different licensing requirements for optical dispensers, enforcement of prescription device sales has usually been left to the state in which the company selling the contact lens is located.”³⁷ However, that does not mean the FDA is either passive or powerless. In a 1998 letter, the FDA noted that it had received complaints about sales of contact lenses by mail without a prescription and confirmed that “FDA is itself investigating alleged violations of Federal law as a basis for possible action.”³⁸ In 2000, the agency reportedly launched an investigation of 1-800 Contacts, as well as 96 other companies suspected of selling by mail various types of prescription devices without first obtaining prescriptions.³⁹

Even with a prescription requirement for replacement contact lenses, it is important to note that federal law does not require that the prescription be written, nor does it define what constitutes a valid contact lens prescription. Instead, state law determines what is included in a valid prescription.

B. Connecticut prescription and prescription release requirements

Connecticut law does not explicitly require that replacement contact lenses be sold pursuant to a prescription.⁴⁰ In fact, the main provision covering where optical goods may be

³⁴ 21 U.S.C. § 352(f).

³⁵ Conn. Gen. Stat. § 21a-106(f).

³⁶ See 21 U.S.C. §§ 353(b)(1), 331(a) and 333.

³⁷ *Buying Contact Lenses on the Internet, by Phone or by Mail: Questions and Answers*, available at <<http://www.fda.gov/cdrh/consumer/buycontactqa.html>>.

³⁸ Letter from Linda Gangloff, Policy Analyst, Executive Secretariat, FDA, to Thomas W. King, Jr., Executive Secretary, Office of the State Board for Optometry, New York (Oct. 21, 1998).

³⁹ Hank Greenberg, *1-800 Contacts in FDA’s Sights*, TheStreet.com (4/11/00).

⁴⁰ Conn. Gen. Stat. § 20-139, entitled Purpose and legislative policy, states in general terms that regulation is required of optical appliances, eyeglasses, lenses, and all aids to human vision sold, dispensed, or supplied in the state and that persons “filling prescriptions having to do with optical glasses from given formulas, and kindred products” shall have the education, skill,

sold, while requiring the supervision of an optician for production or reproduction of optical glasses or kindred products to personalized given formulas, does not require that this be done pursuant to a prescription.⁴¹

Neither the Connecticut statute for optometry, the statute for opticians, nor the Uniform Food and Drug Act defines a prescription.⁴² The Connecticut Pharmacy Practice Act defines a prescription as “a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient.”⁴³

Connecticut law requires that a practitioner of the healing arts, including optometry, release to a patient or his authorized representative a copy of the patient’s health record, including “contact lens specifications based on examinations and final contact lens fittings given within the preceding three months or such longer period of time as determined by the provider but no longer than six months,” unless the provider “reasonably determines that the information is detrimental to the physical or mental health of the patient.”⁴⁴ This strongly suggests that the legislature intended consumers to have the option to purchase lenses separately from the purchase of an eye examination.

If the Board determines that a prescription is required for the purchase of replacement lenses, it would then have a legal means of recourse against stand-alone firms that sell lenses without a prescription, even if those firms were not licensed in Connecticut. States have pursued direct enforcement of their prescription requirements in the recent past. For example, the Texas Optometry Board brought suit against a Florida mail order contact lens seller for violating the Texas statute requiring an unlicensed seller to obtain a complete physical copy of the patient’s prescription before providing the lenses to the patient. The parties ultimately settled, with the seller agreeing to refrain from selling lenses without a proper prescription.⁴⁵

C. Other consumer protection laws

and ability to properly fill any such formulas and shall be licensed. This section imposes no specific licensing or prescription requirements, however.

⁴¹ Conn. Gen. Stat. § 20-150.

⁴² Conn. Gen. Stat. §§ 20-127 to 20-138d (optometry); §§ 2-139 to 20-162 (opticians); §§ 21a-91 to 21a-120 (Uniform Food, Drug and Cosmetic Act).

⁴³ Conn. Gen. Stat. § 20-571(23).

⁴⁴ Conn. Gen. Stat. § 20-7c(b) & (c).

⁴⁵ See *Lens Express, Inc. v. Lois Ewald, as Executive Director of Texas Optometry Board*, 907 S.W.2d 64 (Ct. App. Tx. 1995) (describing history of proceedings).

A variety of other laws and regulations help protect contact lens consumers and ensure that customers purchasing contact lenses from sources other than doctors receive the lenses that are specified in the prescription.

Consumers have relatively easy recourse if an Internet or mail order firm fails to deliver the proper lenses. Unlike the situation with prescription drugs, consumers can easily determine if they have received the correct product by checking the box to ensure that it matches the prescription. In some instances, even if the consumer does not notice that he or she received the incorrect product, the customer may well discover the error when trying to wear the lenses. The customer can then simply remove the incorrect lens. Obviously, this does not rise to the kind of serious risk of harm as would occur if a consumer took the wrong prescription drug.

The Federal Trade Commission has authority under Section 5 of the FTC Act to bring an enforcement action against a contact lens seller who makes false or misleading claims about the products or services it provides.⁴⁶ For example, the Commission has taken action pursuant to Section 5 against online pharmacies for making deceptive claims.⁴⁷ The Commission also has authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers and is not outweighed by countervailing benefits to consumers or to competition.⁴⁸

V. The costs and benefits of licensing stand-alone sellers of replacement lenses

Federal and state regulations already seek to ensure that lens wearers receive the lenses prescribed by their doctors. As long as these regulations are enforced, prescription requirements ensure that lens wearers return to the doctor for regular eye exams, regardless of where the customer purchases replacement lenses. To determine whether additional incremental regulation of stand-alone replacement lens sellers beyond the prescription requirement would enhance

⁴⁶ 15 U.S.C. § 45. In addition, Section 12 of the FTC Act prohibits the false advertisement of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52.

⁴⁷ The Commission brought a complaint against operators of a group of online pharmacies that falsely claimed to be a full service clinic with a national network of physicians. *International Outsourcing Group, Inc.* (File No. 992 3245) (July 12, 2000). The Commission has also brought numerous cases challenging claims for medical devices. See, e.g., *London International Group, Inc.*, C-3800 (Apr. 7, 1998) (consent order) (challenging claims that Ramses condoms are 30% stronger than leading brand and break 30% less often); *United States v. Lifestyle Fascination, Inc.*, No. 97-1487 (CSF) (D.N.J. Mar. 27, 1997) (stipulated permanent injunction and \$60,000 civil penalty) (challenging representations for pain relief device and other products).

⁴⁸ 15 U.S.C. § 45(n); also see Unfairness Policy Statement, appended to *International Harvester Co.*, 104 F.T.C. 949, 1070 (1984).

consumer welfare, it is necessary to consider what additional costs and benefits the additional regulation might create.

A. Costs of licensing stand-alone replacement lens sellers could be substantial

1. Connecticut requirements

Connecticut law, Conn. Gen. Stat. § 20-150, provides “[n]o optical glasses or kindred products or other instruments to aid vision which are produced or reproduced to personalized given formulas, shall be sold at retail except under the supervision of a licensed optician and in a registered optical establishment, office or store. An optical establishment, office or store is defined as meaning one the owner of which has had issued to him an optical license selling permit.”⁴⁹

To obtain a license as an optical establishment, the retail seller of optical glasses or kindred products produced or reproduced to a personalized given formula must be under the direct supervision of a licensed optician.⁵⁰ These permits cost \$250 and are generally valid for one year, although they are terminated immediately if the licensed optician of record disassociates himself from the establishment. Holders of such permits are permitted to use the term “optician.”⁵¹

The statute defines a licensed optician as “[o]ne having a knowledge of optics and skilled in the technique of producing and reproducing ophthalmic lenses and kindred products and mounting the same to supporting materials and the fitting of the same to the eyes.”⁵² To obtain a license as an optician, a candidate must have four years of approved apprenticeship or an Associate’s degree in ophthalmic dispensing from an approved school and have passed the American Board of Opticianry’s National Opticianry Competency examination, the National Contact Lens Examination, and the Connecticut Practical Examination.⁵³

⁴⁹ When citing this law in its petition for declaratory ruling, Johnson & Johnson omitted the crucial limitation on this provision, namely that it covers only sales of optical devices that *are produced or reproduced to personalized given formulas*.

⁵⁰ Conn. Gen. Stat. § 20-151.

⁵¹ Conn. Gen. Stat. § 20-153.

⁵² Conn. Gen. Stat. § 20-145.

⁵³ Conn. Gen. Stat. § 20-146. *See also* Connecticut Department of Health, Detailed Information for Optician Licensure, <<http://www.ct-clic.com/detail.asp?code=1746>>. Section 20-146 also permits an optician licensed in another state to be eligible for a license in Connecticut without examination if the other state has licensing requirements similar to or higher

The Connecticut statute and regulations apply when a retail seller of ophthalmic lenses and kindred products is himself producing or reproducing lenses to "personalized given formulas."⁵⁴ Connecticut's regulatory regime for opticians thus focuses on the producing and reproducing of lenses.⁵⁵ However, once a patient has been fitted with contact lenses by an optometrist or ophthalmologist, the patient merely purchases replacement contact lenses that come prepackaged from the manufacturer and which are not produced or reproduced to a personalized given formula by the seller.⁵⁶ Providing replacement lenses in sealed packages from manufacturers does not involve producing or reproducing lenses and clearly does not require the seller to produce or reproduce lenses to "personalized given formulas"—which is the practice, under the statute, that must be licensed.

If these licensing regulations nevertheless are applied to stand-alone sellers of replacement lenses, such sellers would have to arrange for a licensed optician to supervise their operations and pay a \$250 fee. The need to employ an optician would likely be a costly proposition for a stand-alone seller of replacement lenses. Because such firms do not sell eyeglasses or conduct contact lens fittings, they may not already have an optician on staff. Alternatively, a large operation may not have a sufficient number of opticians to satisfy the

than those of Connecticut.

⁵⁴ A regulation by the Board of Opticians defines contact lenses and says that the "sale of contact lenses in the state of Connecticut is an inclusion under the provision that optical glasses, instruments and kindred products to aid vision may be sold only by licensed opticians" Conn. Agencies Regs. § 20-141-10. Assuming that this regulation refers to § 20-150, based on the statute's specific limitation to optical glasses and kindred products "produced or reproduced to personalized given formulas," this regulation means that contact lenses produced or reproduced to personalized given formulas must also be sold only by licensed opticians.

⁵⁵ See, e.g., Conn. Agencies Regs. §§ 20-141-1, Experience in the producing and mounting of ophthalmic lenses, and 20-141-2, Experience in the fitting of ophthalmic lenses to the eyes by mechanical manipulation. Both of these regulations discuss the grinding, polishing, and forming of lenses and the fitting of ophthalmic lenses to the individual wearer. In fact, the provision on mechanical manipulation specifies that it covers "the casting or fitting of contact lenses;" it does not discuss supplying prepackaged lenses to a customer who has already been fitted for them by an eye care professional.

⁵⁶ It is instructive to compare the statute's wording with the Food and Drug Act's definition of a custom device. See 21 U.S.C. § 360j(b) (a custom device is one that is generally not available in finished form for purchase or dispensing upon prescription). In *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 599 (D.C. Cir. 1985), the manufacturers argued that lenses were custom devices but the court upheld the FDA's conclusion that contact lenses for "all but the most pathological eyes" are not custom devices because they are replicated again and again and are generally available.

state's "supervision" requirement.⁵⁷ Therefore, a requirement that all contact lens sellers obtain an optical establishment permit and an optician's, optometric, or medical license would likely impose a potentially significant additional (and likely unnecessary) cost on these types of alternative sellers.

2. Similar licensing regulations in other professions often raise costs

We know of no study that directly assesses the impact of optical licensing on costs or prices of contact lenses in general or replacement lenses in particular. However, the idea that licensing requirements create additional costs for consumers is hardly novel or unique to replacement contact lenses. In assessing the impact of licensing in this area, it is helpful to consider the effects of licensing on consumer costs in other markets served by regulated professionals. We are more confident that licensing will raise prices for consumers of replacement lenses because we observe that professional licensing tends to raise prices in many other markets where it has been implemented. These price increases should be weighed against any consumer benefits created by occupational licensing to assess whether incremental increases in licensing improve consumer welfare.

Occupational licensing necessarily involves some restriction on the ability of individuals to enter an occupation. This is accomplished through the need for government permission and the demonstration of some minimum degree of competency. The stated motivation for licensing is the desire to maintain or increase the quality of service provided by the professionals being regulated. Business practice restrictions, such as limits on the commercial practice of optometry or restrictions on business relationships between optometrists and opticians, have similar rationales and effects as licensing.

By restricting the supply of professionals into an occupation, licensing tends to raise their wages, which in turn can lead to higher output prices. Licensing and various business practice restrictions can also lead to higher prices by limiting the availability of lower cost suppliers to consumers. Studies of the price effects of licensing are limited to those industries where a well-defined product can be identified. Studies of licensing in dentistry, perhaps the most analyzed of

⁵⁷ Connecticut appears to have construed section 20-153's supervision requirement stringently in the past. For example, the Board of Examiners for Opticians successfully brought a proceeding against a chain of optical shops on the basis that the shops were open without having a licensed optician on the premises at all times, even if the shops were not engaging in the activities that must be performed under the direct supervision of a licensed optician when the optician was absent. *U.S. Vision, Inc. v. Board of Examiners for Opticians*, 545 A.2d 565 (Ct. App. Ct. 1988). This raises the possibility that a stand-alone seller of replacement lenses would be required to have a Connecticut optician supervise operations at all times, even while the seller was not engaging in the activities that, according to Connecticut law, must be performed by a licensed optician.

the professions, find price increases of from 4 percent to 15 percent.⁵⁸ Studies of the eye care market report price increases from 5 percent to 33 percent that are attributable to a variety of advertising and commercial practice restrictions.⁵⁹

Laws, regulations, or other rules that unnecessarily require firms or customers to employ members of the regulated professions for specified tasks can also raise consumer prices. Several states, for example, have considered measures that would require borrowers to hire attorneys to represent them in real estate loan closings, even in situations such as refinancings that involve little legal work on behalf of the borrower. Based on evidence from several states, the Federal Trade Commission and U.S. Department of Justice have concluded that such requirements would typically increase prices to borrowers by between \$150 and \$400.⁶⁰

Licensing can either increase or decrease service quality.⁶¹ While the restriction of supply from licensing typically leads to a higher average competence level for the professionals allowed to practice, the higher price for their services can lead to less utilization by consumers. This

⁵⁸ Carolyn Cox and Susan Foster, *The Costs and Benefits of Occupational Regulation*, Federal Trade Commission (1990), at 31; Morris Kleiner and Robert Kudrle, *Does Regulation Affect Economic Outcomes?: The Case of Dentistry*, THE JOURNAL OF LAW AND ECONOMICS, Oct. 2000, at 547-82.

⁵⁹ Cox and Foster, *supra* note 58, at 31. But compare a more recent study by Philip Parker ('Sweet Lemons: Illusory Quality, Self-Deceivers, Advertising, and Price', JOURNAL OF MARKETING RESEARCH, Vol.32, Aug. 1995, at 291-307), suggesting that the results of some of the earlier studies of the eye care market may be sensitive to alternative model specifications.

There is a larger range of studies assessing the effects of licensing restrictions on wage rates, although the results tend to be mixed. Using a more sophisticated test for the stringency of licensing restrictions, Steven Tenn, finds that licensing is an effective barrier to entry into the legal profession and that it tends to increase the wages of lawyers appreciably. See Steven Tenn, *Three Essays on the Relationship Between Migration and Occupational Licensing* (2001) (unpublished Ph.D. dissertation, Univ. of Chicago).

⁶⁰ See Letter from Charles A. James and Timothy J. Muris to the Ethics Committee of the North Carolina Bar Re North Carolina State Bar Opinions Restricting Involvement of Non-Attorneys in Real Estate Closings and Refinancing Transactions (Dec. 14, 2001) <<http://www.ftc.gov/be/V020006.htm>>; Letter from Joel I. Klein and William J. Baer to the Supreme Court of Virginia Re Proposed UPL Opinion #183 (Jan. 3, 1997) <<http://www.ftc.gov/be/v960015a.htm>>.

⁶¹ Morris Kleiner, *Occupational Licensing*, JOURNAL OF ECONOMIC PERSPECTIVES, Fall 2000, at 198. Economic theory also cautions that increased quality does not always make consumers better off. The slightly higher quality of licensed professionals may not be worth the significant extra cost to certain individuals, who would rather trade off some minimal reduction in quality for a lower price.

indeterminacy is reflected in the empirical research, where no clear link between licensing and service quality has been demonstrated.⁶²

3. Adverse effects would be concentrated on customers who prefer stand-alone sellers of replacement lenses

Most stand-alone sellers represent unique alternative distribution channels: Internet and mail order. Internet and mail order offer some consumers a combination of price and convenience that they value highly. Because licensing may impose additional costs on stand-alone sellers of replacement lenses, it has the potential to curtail these consumer benefits by inducing mail-order firms to charge higher prices or exit the Connecticut market entirely.

Data on price differences between mail order and other sellers of replacement lenses are sparse. The most recent data are from a nationwide survey by SRI commissioned by the state attorneys general as part of the multidistrict litigation. In 1998, the average price of a six-lens multipack purchased via mail order was \$19.90, compared to an average of \$23.76 for lenses purchased from ophthalmologists, optometrists, and optical chains – a 19 percent difference.⁶³ The survey also reported that price differences matter for most consumers, even if they were not currently mail-order customers. Of the survey respondents who had not purchased their most recent set of contact lenses via mail order, 62 percent said they would do so if the mail-order price were 15 percent less than the last price they paid, and 78 percent said they would do so if the mail-order price were 25 percent less. The SRI data also suggest, however, that consumers who purchase their lenses from traditional suppliers could achieve equivalent savings at a mass merchant discounter, such as Wal-Mart, Costco, or BJ's; the average price at such retailers was \$19.98.⁶⁴

⁶² Of the 11 studies surveyed by Cox and Foster, *supra* note 58, at 26-27, only two reported a positive association between the strength of restrictions on practitioners and quality. More recent studies are no more supportive of the purported tendency of licensing to improve service quality. In a study of dental licensing, Kleiner and Kudrle, *supra* note 58, found that more stringent licensing did not result in improved dental outcomes among a sample of 464 new Air Force recruits. Similarly, Gary Colbert and Dennis Murray, (*State Accountancy Regulations, Audit Firm Size, and Auditor Quality: An Empirical Investigation*, 16(3) JOURNAL OF REGULATORY ECONOMICS, Nov. 1999, at 267-85) found no association between audit quality and variations in the strictness of state accountancy regulations. Defining quality can be very difficult, and typically it is studied for those outcomes where empirical definitions are feasible. There thus remains a large number of situations that have not been investigated.

⁶³ It is not clear whether the mail-order price includes shipping and handling. Survey takers were instructed to tell respondents to omit shipping and handling charges only if the respondent asked about the issue. In addition, some mail-order firms offer free shipping and handling.

⁶⁴ Susan Russell, *Nationwide Survey of Contact Lens Wearers* (1999).

The principal difference between the mail-order firms and the mass merchandisers thus appears to be the delivery mode, not the price. The two delivery modes involve significantly different convenience costs for consumers. To enjoy the price savings at a mass merchandiser, the consumer has to make a trip to the store and often endure a wait in a line. Multiple trips may be necessary if the store does not have the particular lenses in stock and must order them. Consumers who opt for mail order, on the other hand, can have replacement lenses delivered simply by calling a toll-free phone number or visiting a web site. The inconvenience of visiting a mass merchandiser is likely unimportant for consumers who attach a low value to their time or who were going to the store to purchase other items anyway. It could be substantial, however, for consumers who attach high value to their time, make a special trip to the store just to obtain replacement lenses, or live in areas distant from mass merchandisers.

How much value might some customers place on the convenience of mail order? Research in transportation economics suggests that individuals value urban travel time by automobile and public transit at between 75 and 178 percent of their wage rate.⁶⁵ At the average private hourly wage of \$14.61 (December 2001), an hour-long trip to Wal-Mart to buy replacement lenses has an implicit time cost of between \$10.96 and \$26.00.⁶⁶ That figure represents a markup of between 50 and 130 percent over the price of a multipack. Therefore, the convenience cost of policies that impede entry by mail-order replacement lens sellers could be substantial.

B. Licensing stand-alone replacement lens sellers offers no additional consumer protection

Licensing stand-alone replacement contact lens sellers is unlikely to diminish any of the genuine health risks associated with contact lenses. Licensing the lens seller will not induce individuals to comply with the wearing or disposal schedules recommended by the doctor. Licensing the lens seller will also not induce individuals to have more frequent eye exams.

Licensing is not necessary to ensure sellers follow prescriptions. Concerns about quality of care related to follow-up examinations can be addressed by enforcing contact lens prescriptions, rather than by inhibiting sales by non-traditional providers. Requiring customers to return to an eye care professional to purchase replacement lenses does not reduce the individual's incentive or ability to wear lenses for too long. Moreover, Connecticut law does not allow

⁶⁵ Clifford Winston, *Conceptual Developments in the Economics of Transportation: An Interpretive Survey*, 23 JOURNAL OF ECON. LIT., 1985, at 77.

⁶⁶ Average wage is from Council of Economic Advisers, *Economic Report of the President* (2002), at Table B-47.

opticians to examine eyes or treat eye problems, so forcing consumers to purchase replacement lenses from an optician does not advance the health goal of more frequent eye exams.⁶⁷

C. Licensing may produce unintended consequences harmful to consumers

Several commenters in the FTC Rule review noted that fostering competition in contact lens sales can be expected to increase the quality of care rather than decrease it.⁶⁸ To the extent that it raises costs for stand-alone sellers of replacement lenses, licensing of opticians and optical establishments may actually increase the incidence of health problems associated with contact lens use.

Stand-alone sellers of replacement lenses derive the bulk of their revenue from the sale of disposable lenses. As a threshold matter, there seems to be consensus that disposable lenses, especially when worn properly, are generally healthier than conventional daily wear lenses.⁶⁹ Doctors have reported that frequent replacement of lenses has yielded a significant decrease in eye infections and inflammation among their patients who wear disposables.⁷⁰

However, many consumers who wear disposable lenses over-wear their lenses, which diminishes the health benefits of such lenses. One survey revealed that fewer than 50 percent of consumers comply with the recommended wearing schedule.⁷¹

Importantly, fifty-seven percent of consumers stated they would replace their lenses more frequently if the lenses cost less.⁷² Moreover, 30 percent specifically identified cost savings as the reason they over-wear their lenses, stating they “try to save money by wearing [their] contact lenses for more days than [their] doctor recommends before disposing of them.”⁷³ Twenty-two percent said they do not replace their lenses as often as they should because “purchasing them is

⁶⁷ See Conn. Gen. Stat. § 20-127(3) (defining the practice of *optometry* to include the examination of the human eye and eyelid for the purpose of diagnosis).

⁶⁸ Comment from NAOO (#119), at 11-12; Comment from State Attorneys General (#118), at 7.

⁶⁹ See Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 134-35 (citing studies).

⁷⁰ *Id.* at 135-36.

⁷¹ McKinsey & Company, Consumer Fact Pack, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 92.

⁷² *Id.* at 97.

⁷³ *Id.*

inconvenient.” Not only will many disposable lens wearers over-wear their lenses in order to save money, but studies also suggest that more consumers would opt to switch from conventional lenses to the healthier disposable lenses if disposables cost less.⁷⁴

Increasing the cost and inconvenience of obtaining disposable replacement lenses may induce more individuals to over-wear their replacement lenses; decreasing the cost and inconvenience may induce more individuals to comply with eye doctors’ instructions. Imposing licensing requirements on stand-alone sellers of replacement lenses thus has the potential to increase health risks for consumers.

D. Licensing out-of-state sellers of replacement lenses

One potential additional benefit of licensing out-of-state sellers is that the license gives the state additional leverage to protect consumers. If an out-of-state seller fails to comply with prescription requirements, perhaps by sending consumers the wrong lenses or selling lenses without receiving a valid prescription, then the State could prompt compliance by threatening to revoke the seller’s license. If the seller still refuses to comply, the State could revoke the license, thus protecting consumers from the health risks involved in dealing with that seller.

It is doubtful that licensing is necessary to protect consumers in this way. Even in the absence of licensing, both consumers and government have significant avenues of recourse if an out-of-state seller fails to comply with prescription requirements.⁷⁵ The Board could also suggest that the Connecticut legislature authorize it to adopt additional safeguards that would be less restrictive, such as registration. A registration system, unlike licensing, would not require that individuals or firms that want to sell replacement lenses fulfill expensive and unnecessary requirements in order to do so. Rather, replacement lens sellers would merely file their names and other required contact information with the Board. The Board would thereby know who is selling replacement lenses in Connecticut and would have sufficient contact information in the event that a particular seller engages in practices that create health risks for consumers. For this reason, it is doubtful that out-of-state sellers present any unique consumer protection problems for which state licensing is a necessary solution. And, any theoretical increase in enforcement authority is almost certainly outweighed by the additional costs likely to be passed on to Connecticut consumers as a result of requiring replacement lens sellers to be licensed in Connecticut.

VI. The prescription requirement

⁷⁴ See Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 138 (citing study).

⁷⁵ See Section IV above.

The third question asks whether a contact lens seller that sells lenses to a Connecticut consumer without first receiving a prescription from a licensed physician or optometrist is in compliance with Connecticut law. The way in which the prescription requirement is interpreted and enforced could have a substantial impact on competition.

The real prescription issue in this proceeding is not whether a prescription should be required. The key question is what it means to say that the contact lens seller must *receive* this prescription from a licensed physician or optometrist. This question can be answered in a way that either restricts or promotes competition.

According to the FDA's guide for consumers regarding the purchase of contact lenses over the Internet, a lens seller does not have to receive a written prescription to comply with the federal prescription device regulation. The FDA indicates that if the company checks with the doctor, the company has satisfied the prescription requirement. The FDA guide notes that websites allow the purchaser to fill out a chart with the ordering information and supply contact information for the purchaser's doctor. Thus, the federal prescription requirement may be satisfied by the ability to check with the doctor orally. Connecticut's requirements are similar, since, by statute, a prescription can be transmitted either orally, in writing, or by electronic means.

It is clear that sales of lenses by alternate channels can easily satisfy federal and state prescription requirements. Consumers who wish to order lenses by phone, mail, or Internet can either mail in, call in, fax, or provide in electronic form their prescription information to the lens seller. The lens seller can contact the eye care provider in the same ways, if prescription verification is necessary. Likewise, a valid prescription, communicated to the seller by the patient, can be presumed verified if the doctor is contacted and given sufficient opportunity to correct any errors.

This multiplicity of ways to satisfy a prescription requirement is procompetitive in that it provides consumers with a number of ways in which to obtain their replacement lenses, thus allowing the market to respond to genuine consumer demand. The FTC staff believe it would be detrimental to competition and consumers to overly restrict the ways in which prescription information for replacement lenses may be transmitted.

Similarly, prescriptions that are narrowly drawn so as to favor one contact lens over another, absent sound medical justification, or that have unduly short expiration dates, may also raise significant anticompetitive problems. To the fullest extent consistent with necessary health standards, consumers should be allowed the widest latitude to receive replacement lenses from whichever providers they choose.

In neither the Rule review nor the multidistrict litigation has anyone suggested that consumers should be permitted, or that they are remotely likely to try, to obtain contact lenses without first being fitted for them by an eye care professional. Instead, the crucial question is whether consumers should be able to obtain replacement contact lenses using the prescription

information they have from the box of lenses for which they were initially professionally fitted. Both industry representatives and government regulators have informed us that there is a strong consumer demand to obtain replacement contact lenses in this manner.

The position of the staff of the Commission is that strong consumer demands should not be thwarted lightly. The evidence suggests that the health concerns motivating the prescription requirement are satisfied if the contact lens seller receives a valid prescription, however that information is transmitted. If the Board disagrees with this assessment, we nevertheless urge the Board to carefully weigh the health effects of a more restrictive policy against the potential harm to competition and consumer choice.

VII. Conclusion

The staff of the Federal Trade Commission has extensive expertise in analyzing occupational regulation in general and eyewear issues in particular. When assessing the impact of a regulatory change, we typically examine the incremental costs and benefits that would be created by an increase or decrease in regulation.

Based on the evidence we have seen, we believe that requiring stand-alone sellers of replacement contact lenses to obtain Connecticut optician and optical establishment licenses would likely increase consumer costs while producing no offsetting health benefits. Indeed, such licensing could harm public health by raising the cost of replacement contact lenses, inducing consumers to replace the lenses less frequently than doctors recommend or to substitute other forms of contact lenses that pose greater health risks.

An overly narrow interpretation of Connecticut law on these issues will likely have two significant detrimental effects: (1) it will restrict the choices available to Connecticut consumers, raise their costs, and reduce their convenience unnecessarily, and (2) it will serve as a barrier to the expansion of Internet commerce in the State of Connecticut. Current federal and state prescription requirements and consumer protection laws are sufficient to address the health problems associated with contact lens use. Such requirements can be implemented in ways that are either procompetitive or anticompetitive, and the FTC staff urge the Board to implement the prescription requirement in a way that protects consumers health, promotes competition, and maximizes consumer choice.

Respectfully submitted,

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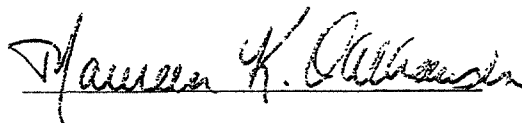
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